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Dated: 3/9/04 Signature: Ceresa Soldano  
(Ceresa Soldano)

Docket No.: YU-P02-011  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Flavell et al.

Application No.: 10/627595

Confirmation No.: 2979

Filed: July 25, 2003

Art Unit: 3732

For: IRAK-M IS A NEGATIVE REGULATOR OF  
TOLL-LIKE RECEPTOR SIGNALING

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

Pursuant to MPEP 609, copies of the references cited on the PTO/SB/08 are not provided herewith. Copies of these references were filed in the parent application serial number 10/340545 filed on January 9, 2003.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent,

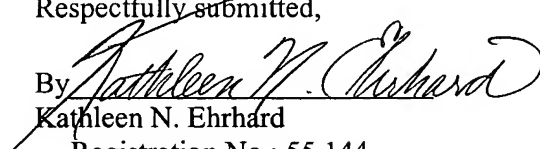
publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. YU-P02-011.

Dated: March 9, 2004

Respectfully submitted,

By   
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PTO/SB/08A (10-01)

Approved for use through 10/31/2002.OMB 0651-0031

U. S. Patent and Trademark Office: U. S. DEPARTMENT OF COMMERCE

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<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			<b>Application Number</b>	10/627595	
			<b>Filing Date</b>	July 25, 2003	
			<b>First Named Inventor</b>	Richard A. Flavell	
			<b>Art Unit</b>	3732	
			<b>Examiner Name</b>	Not Yet Assigned	
<b>Sheet</b>	1	of	2	<b>Attorney Docket Number</b>	YU-P02-011

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	6,262,228	07-17-01	Cao	
	AB	20020049300	04-25-02	Cao	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> <i>(if known)</i>				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See attached Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AC	Cao, Z. et al. IRAK: a kinase associated with the interleukin-1 receptor. Science 271, 1128-1131 (1996).	
	AD	Kanakaraj, P. et al. Interleukin (IL)-1 receptor-associated kinase (IRAK) requirement for optimal induction of multiple IL-1 signaling pathways and IL-6 production. J. Exp. Med. 187, 2073-2079 (1998).	
	AE	Kawai, T. et al. Unresponsiveness of MyD88-deficient mice to endotoxin. Immunity 11, 115-122 (1999).	
	AF	Kobayashi, K. et al. IRAK-M is a negative regulator of Toll-like receptor signaling. Cell 110, 191-202 (2002).	
	AG	Medzhitov, R. et al. MyD88 is an adaptor protein in the hToll/IL-1 receptor family signaling pathways. Mol. Cell 2, 253-258 (1998).	
	AH	Muzio, M. et al. IRAK (Pelle) family member IRAK-2 and MyD88 as proximal mediators of IL-1 signaling. Science 278, 1612-1615 (1997).	
	AI	Wesche, H. et al. MyD88: an adapter that recruits IRAK to the IL-1 receptor complex. Immunity 7, 837-847 (1997).	
	AJ	Wesche, H. et al. IRAK-M is a novel member of the Pelle/interleukin-1 receptor-associated kinase (IRAK) family. J. Biol. Chem. 274, 19403-19410 (1999).	

<b>Examiner Signature</b>		<b>Date Considered</b>	
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				Art Unit	3732
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	YU-P02-011

	AK	Zhang, F.X. et al. Bacterial lipopolysaccharide activates nuclear factor-kappaB through interleukin-1 signaling mediators in cultured human dermal endothelial cells and mononuclear phagocytes. J. Biol. Chem. 274, 7611-7614 (1999).	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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